



P.B. 5010 - Patentan 2
2280 HV Rijswijk (ZH)
☎ (070) 340 2040
Tx 31651 speed
FAX (070) 340 3010

Europäisches
Patentamt
Zweigstelle in
Den Haag
Recherchen-
abteilung

European
Patent Office
Branch
The Hague
Search
Division

Office européen
des brevets
Département A
La Haye
Division de la
recherche

D4

Kiddle, Simon John
Mewburn Ellis LLP
York House,
23 Kingsway
London WC2B 6HP
GRANDE BRETAGNE

16/11/04	EXTD FOR
LY'D	SJK
TO 1	2
SJK	

RECEIVED
- 8 OCT 2004
MEWBURN ELLIS LLP

Date/Date
06.10.2004

Zeichen/Ref./Rif.

SJK/FP5842554

Anmeldung Nr./Application No./Demande n°/Patent Nr./Patent No./Brevet n°
99933581.3-1222/US9914486

Anmelder/Applicant/Demandeur/Patentinhaber/Proprietar/Titulaire
Virologic, Inc.

COMMUNICATION

The European Patent Office herewith transmits the partial European search report under Rule 46(1) EPC relating to the above-mentioned European patent application.

Copies of the documents cited in the search report are enclosed.

The applicant's attention is drawn to the following:

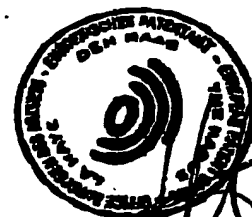
The search Division informs the applicant that if the European search report is also to cover inventions other than the invention first mentioned in the claims, a further search fee must be paid for each of these inventions, within ONE MONTH after notification of this communication.

If the application has been filed up to 30 June 1999, the search fee in force before 01 July 1999 (EUR 869.--) or the equivalent applicable on the date of payment is payable.

This applies also to the search fees requested under Rule 46(1) EPC.
See also OJ EPO 08/1999, 405.

☐ The abstract was modified by the Search Division and the definitive text is attached to the present communication.

☒ Additional set(s) of copies of the documents cited in the European search report is (are) enclosed as well.



Note to users of the automatic debiting procedure:

Unless the EPO receives prior instructions to the contrary, the search fee(s) will be debited on the last day of the period for payment. For further details see the Arrangements for the automatic debiting procedure, Supplement to OJ EPO 02/1999.

REGISTERED LETTER

EPO Form 1507.2 (07.99)

BEST AVAILABLE COPY



European Patent
Office

**SUPPLEMENTARY
PARTIAL EUROPEAN SEARCH REPORT**

under Rule 46, paragraph 1 of the European Patent Convention
Application Number
EP 99 93 3581

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (INCL.6)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
X	WO 97/27332 A (INNOGENETICS NV ; STUYVER LIEVEN (BE); LOUWAGIE JOOST (BE); ROSSAU RUD) 31 July 1997 (1997-07-31)	1-7	C12Q1/68 C12Q1/70 C12N13/00 C07H21/02 C07H21/04 A01N43/04
Y	* page 4, line 15 - page 5, line 11 *	17, 18, 20-31	
	* page 6, line 16 - page 7, line 15 *		
	* page 13, line 26 - line 29 *		
	* page 22, line 19 - line 21 *		
	* tables 1-3 *		
D, Y	WO 97/27319 A (VIROLOGIC INC) 31 July 1997 (1997-07-31)	17, 18	
	* claims 1, 5, 12, 28, 32, 33, 88, 90, 93 *		
	-/-		
			TECHNICAL FIELDS SEARCHED (INCL.6)
			C12Q
LACK OF UNITY OF INVENTION			
The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:			
see sheet B			
The present partial European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims.			
3	Place of search The Hague	Date of completion of the search 24 September 2004	Examiner Schmitt. A
CATEGORY OF CITED DOCUMENTS		T: theory or principle underlying the invention E: earlier patent document, but published on, or after the filing date D: document cited in the application L: document cited for other reasons A: technological background O: non-written disclosure P: intermediate document	
X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background O: non-written disclosure P: intermediate document			

EP0 FORM 1503 (3.02) (Rev. 2.01)



DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int. Cl. 6)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
Y	IVERSEN A K N ET AL: "MULTIDRUG-RESISTANT HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 STRAINS RESULTING FROM COMBINATION ANTIRETROVIRAL THERAPY" JOURNAL OF VIROLOGY, THE AMERICAN SOCIETY FOR MICROBIOLOGY, US, vol. 70, no. 2, 1 February 1996 (1996-02-01), pages 1086-1090, XP002031823 ISSN: 0022-538X * the whole document *	17, 18, 22-25, 28-31	
A		1-7, 20, 21, 26, 27	
Y	FITZGIBOON J E ET AL: "HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 POL GENE MUTATIONS IN AN AIDS PATIENT TREATED WITH MULTIPLE ANTIRETROVIRAL DRUGS" JOURNAL OF VIROLOGY, THE AMERICAN SOCIETY FOR MICROBIOLOGY, US, vol. 67, no. 12, December 1995 (1995-12), pages 7271-7275, XP002934804 ISSN: 0022-538X * the whole document *	20, 21, 24-27	TECHNICAL FIELDS SEARCHED (Int. Cl. 6)
Y	CLERCQ DE E: "DEVELOPMENT OF RESISTANCE OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) TO ANTI-HIV AGENTS: HOW TO PREVENT THE PROBLEM?" INTERNATIONAL JOURNAL OF ANTIMICROBIAL AGENTS, AMSTERDAM, NL, vol. 9, no. 1, 1997, pages 21-36, XP000878561 ISSN: 0924-8579 * the whole document *	17, 18	
A		1-7, 20-31	

3

EPO FORM 1508 (02/92) PHE-10



European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number
EP 99 93 3581

DOCUMENTS CONSIDERED TO BE RELEVANT		Relevant to claim	CLASSIFICATION OF THE APPLICATION (In.Cls)
Category	Citation of document with indication, where appropriate, of relevant passages		TECHNICAL FIELDS SEARCHED (In.Cls)
A	KANKI P J ET AL: "VIROLOGY OF HIV-1 AND HIV-2: IMPLICATIONS FOR AFRICA" AIDS, LONDON, GB, vol. 11, no. SUPPL B, 1997, pages S33-S42, XP008035289 ISSN: 0269-9370 * the whole document *		

EPO FORM 1500 (12.02) (PHE/19) 3



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-7, 17, 18, 20-31 (completely)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV reverse transcriptase (HIV-RT) having a mutation/insertion at codon 69, or at codons 69, 41, 215, or at codons 69, 62, 215, or at codons 69, 62, 74, or at codons 69, 41, 215, 210 (210, 75; 62; 62, 210); and method and resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codon(s).

2. claims: 8 - 16, 19 (partially)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 62 or at codon 62 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codon(s).

3. claims: Claims 8 - 16, 19 (partially)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 75 or at codon 75 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codons.

4. claims: Claims 8 - 16, 19 (partially)



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 77 or at codon 77 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codons.

5. claims: Claims 8 - 16, 19 (partially)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 116 or at codon 116 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codons.

6. claims: Claims 8 - 16, 19 (partially)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 151 or at codon 151 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codons.

The single general concept possibly linking inventions 1 to 6 appears to be the provision of methods and/or products for assessing drug effectiveness involving HIV-RT having a mutation at a certain codon. Methods and/or products for assessing drug effectiveness involving HIV-RT having a mutation at a certain codon are already disclosed in the prior art (cf. WO 97/27332 A: p. 4, l. 15 - p. 5, l. 6; Tables 1 - 3; cf. IVERSEN A K N et al. (1996): Table 1; cf. FITZGERIBOON J E et al (1995): tables 1, 2; cf. DE CLERCQ E (1997): Tables 2 - 5). Therefore, the Search Division is of the opinion that the above defined single general concept lacks novelty and thus does not represent a single general inventive concept. Hence, the present application lacks unity



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

(Art. 82 EPC).

No further features shared by the 6 inventions listed above could be identified by the Search Division, which would be considered to be special technical features in the sense of Rule 30 EPC. Hence, the 6 inventions listed above are not unitary according to Article 82 EPC.

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 99 93 3581

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

24-09-2004

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9727332	A	31-07-1997	AU 719691 B2	18-05-2000
			AU 1444397 A	20-08-1997
			BR 9704637 A	09-06-1998
			CA 2215073 A1	31-07-1997
			WO 9727332 A1	31-07-1997
			EP 0817866 A1	14-01-1998
			JP 11502727 T	09-03-1999
			US 6331389 B1	18-12-2001
			US 6087093 A	11-07-2000
			US 2003077575 A1	24-04-2003
WO 9727319	A	31-07-1997	AU 732255 B2	12-04-2001
			AU 1952897 A	20-08-1997
			CA 2216126 A1	31-07-1997
			CN 1213407 A	07-04-1999
			DE 69711584 D1	08-05-2002
			DE 69711584 T2	07-11-2002
			EP 1170380 A2	09-01-2002
			EP 0852626 A1	15-07-1998
			ES 2175355 T3	16-11-2002
			HU 9900388 A2	28-05-1999
			JP 2000503849 T	04-04-2000
			NO 983421 A	25-09-1998
			NZ 331376 A	27-03-2000
			PL 328068 A1	04-01-1999
			RO 118887 B1	30-12-2003
			WO 9727319 A1	31-07-1997

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER: _____**

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.